Major Kidney Clinical Research Studies and Projects Inventory*

Multicenter Trial of SYNSORB Pk® in *E. coli*-Related Hemolytic Uremic Syndrome (HUS)

1. Administrative Data

(a) Name of study/research project and acronym:

Multicenter trial of SYNSORB Pk® in *E. coli*-Related Hemolytic Uremic Syndrome (HUS)

(b) Type of study/research project (randomized clinical trial, epidemiological study, database, etc.):

Randomized clinical trial.

(c) Funding status (currently funded, study/project completed):

Trial completed.

(d) Recruitment status (recruitment completed, currently recruiting):

Recruitment completed.

(e) For studies/project currently recruiting, indicate total sample size/ number currently enrolled, anticipated period of recruitment:

Not applicable.

(f) Data coordinating center principal investigator contact information (mailing address, phone, fax, e-mail address):

Avital Cnaan Ph.D.
Children's Hospital of Philadelphia
Philadelphia, PA
Phone: 215-590-3236,
E-mail: cnaan@email.chop.edu

(g) Number of recruiting sites, list of principal investigators at recruiting sites, and contact information as in (f) above:

Administrative Center:

Howard Trachtman, M.D. (Principal Investigator)

Schneider Children's Hospital
New Hyde Park, NY
Phone: 718-470-3491
E-mail: trachtma@lij.edu

Erica Christen, R.N. (Project Coordinator)
Schneider Children's Hospital
New Hyde Park, NY

Microbiology Core Laboratory:

David Acheson, M.D. (Director)
Ramona Chitrakar
Thao Ngo
Fred Smith
Michelle Nieves
Sam Caraballo
Tufts-New England Medical Center
Boston, MA

Jilma Patrick
University of Maryland
Baltimore, MD

Participating Centers:

See Appendix A.

(h) List of principal investigators at central laboratories/facilities (identify type of central facility) and contact information as in (f) and (g) above:

Microbiology Core Laboratory:

David Acheson, M.D. (Director)
Tufts-New England Medical Center
Boston, MA

(i) Roster of Data and Safety Monitoring Board/Scientific Advisory Committee or other oversight committee(s):

Data Safety Monitoring Board:

Julie Ingelfinger, M.D. (Chairperson); Gladys Hirschman, M.D.; Josephine Briggs, M.D.; John Kusek, Ph.D.; Daniel Cattran, M.D.; Mitchell B. Cohen, M.D.; Katherine Freeman, Ph.D.; Thomas Greene, Ph.D.; Solomon Moshe, M.D.

(j) Private sector support (type of support—e.g., financial, donation of drugs/placebo, etc.):

SYNSORB Biotech, Inc., supplied drug

2. Study Design

For completed studies, a copy of the primary publication can substitute for information on objective, study design, major inclusion criteria, major exclusion, criteria, description of the intervention(s), baseline/eligibility visit schedule (number of visits, major assessments), follow-up contact schedule (frequency, type of visit-phone, in-clinic, major assessments), primary outcome, secondary outcomes, brief summary of power estimates used to justify sample size/duration – including critical assumptions (i.e., effect-size estimates), estimated event rates or rate of change in outcome measure:

See 5. Publications.

3. Data and Biological Sample Resources

(a) Biological samples collected in ongoing studies/research projects (specify the type of sample, e.g., blood, urine, etc., the amount, and the point in the study when samples were collected, e.g., baseline visit #1, baseline visit #2, follow-up visit #1; specify months after randomization/study entry):

Plasma an urine 1-2 ml/sample, collected during hospitalization and on days 7,14, 28, and 60 post-discharge

(b) Biological samples currently in storage from completed trials (grid showing sample collection time, type of sample, amount, and number of study participants sample was collected from, and physical location of where the samples are stored):

All samples described above are stored at -70 degrees in Dr. Acheson's laboratory.

(c) Brief summary of typical informed consent provisions (template informed consent form acceptable), including major variables in participant consents, if applicable (e.g., "use for other studies or not", "allow genetic studies or not."). Does consent include use of samples in other studies that are not part of the main study?

Consent allows storage of specimens and testing in future studies. The samples do not enable performance of any genetic tests.

(d) Data collected (grid of data collection by time/clinic visit with specificity on the type of information collected—e.g., quality of life with SF-MOS 36, measurement of kidney function by GFR, serum creatinine measurement, etc.):

(e) Any provisions for distributing resources outside of the study? What is the sharing plan?

Data and resources are open to sharing if request is made to study PI (H. Trachtman)

4. Ancillary Studies

(a) Process and contact person (name, address, phone, fax, and e mail address) for application to perform ancillary studies:

Howard Trachtman, M.D.
Schneider Children's Hospital
New Hyde Park, NY
Phone: 718-470-3491
Fax: 718-470-0887
E-mail: trachtma@lij.edu

(b) List of ancillary studies approved, completed, and ongoing (including source of funding and amount):

Serial measurements of bFGF in plasma and urine; serial measurements of HMG-B1 in plasma and urine

5. List of Publications and Presentations (full citations, also note manuscripts in progress)

Presentations: ASN October 2001 (bFGF data) and ASN 2002 trial (outcomes)

Publications: *JASN* 2002;13:699-707; *JAMA* (under review)

6. Cooperative Agreement, Contract, and Selected Investigator-Initiated NIDDK Supported Studies*

None

Appendix A. Participating Centers and Principal Investigators

Howard Trachtman, M.D.
Schneider Children's Hospital
New Hyde Park, NY

Seth Schulman, M.D.
Children's Hospital of Philadelphia
Philadelphia, PA

James Springate, M.D.
Children's Hospital of Buffalo
Buffalo, NY

Frederick Kaskel, M.D., Ph.D.
Montefiore Medical Center
Bronx, NY

Dilys Whyte, M.D.
State University of NY Hospital at Stony Brook
Stony Brook, NY

Robert Weiss, M.D.
New York Medical College/Westchester County Medical Center
Valhalla, NY

Charles McKay, M.D.
duPont Hospital for Children
Wilmington, DE

Lewis Reisman, M.D.
St. Barnabas Hospital for Children
Livingston, NJ

Eduardo Perelstein, M.D.
Cornell University Medical Center
New York, NY

Manju Chandra, M.D.
North Shore University Hospital
Manhasset, NY

Jose Salcedo, M.D.
St. Joseph's Children's Hospital
Patterson, NJ

Lynne Weiss, M.D.
Robert Wood Johnson University Hospital
New Brunswick, NJ

William Varade, M.D.
State University of NY Rochester Medical Center
Rochester, NY

Douglas Ford, M.D.
Denver Children's Hospital
Denver, CO

James Chan, M.D.
Medical College of Virginia
Richmond, VA

Irene Restaino, M.D.
Children's Hospital of the King's Daughters
Norfolk, VA

Shashi Nagaraj, M.D.
Wake Forest University/North Carolina Baptist Hospita,
Winston-Salem, NC

Victoria Norwood, M.D.
University of Virginia Medical Center
Charlottesville, VA

John Foreman, M.D.
Duke University Medical Center
Durham, NC

Michael Moritz, M.D.
Children's Hospital of Pittsburgh
Pittsburgh, PA

John Mahan, M.D.
Columbus Children's Hospital
Columbus, OH

Marva Moxey-Mims, M.D.
Children's National Medical Center
Washington DC

Barry Warshaw, M.D.
Egleston Children's Hospital
Atlanta, GA

Verna Yiu, M.D.
University of Alberta Hospital
Edmonton, Alberta, Canada

Andrew Brem, M.D.
Rhode Island Hospital
Providence, RI

Sharon Bartosh, M.D.
University of Wisconsin Hospital
Madison, WI

Sharon Andreoli, M.D.
University of Indiana/Riley Children's Hospital
Indianapolis, IN

Lawrence Milner, M.D.
Tufts New England Medical Center
Boston, MA

Jens Goebel, M.D.
University of Kentucky Medical Center
Lexington, KY

Dianne Muchant, M.D.
West Virginia University Medical Center
Morgantown, WV

Coral Hanevold, M.D.
Medical College of Georgia
Augusta, GA

Appendix A.